K031810

SEP - 9 2003

6. 510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of Safe Medical Devices Act 1990 and 21 CFR 807.92.

Contact Person: Patrice Stromberg
Regulatory Affairs Associate
AGA Medical Corporation
682 Mendelssohn Avenue
Golden Valley, MN 55427

Date Prepared: June 11, 2003

Device Name: AMPLATZER® Vascular Plug
Arterial Embolization Device (79KRD)
(21 CFR 870.3300)

Device Description:
The AMPLATZER Vascular Plug is provided sterile and is intended for one-time use. The AMPLATZER Vascular Plug is a self-expandable, cylindrical device made from a Nitinol wire mesh. The device is secured on both ends with platinum marker bands. The delivery system is comprised of a 135 cm long, stainless steel delivery cable and a PTFE loader. The AMPLATZER Vascular Plug is preloaded in a loader and delivered through currently available standard 5 or 6 French guiding catheters. The device will be available in the following sizes.

Order No.	Vascular Plug Diameter	Device Length	Catheter Requirements*		
			Minimum Size	Minimum Inner Diameter	Maximum Length
9-PLUG-004	4 mm	7 mm	5 French	.056"	100 cm
9-PLUG-006	6 mm	7 mm	5 French	.056"	100 cm
9-PLUG-008	8 mm	7 mm	5 French	.056"	100 cm
9-PLUG-010	10 mm	7 mm	6 French	.067"	100 cm
9-PLUG-012	12 mm	8 mm	6 French	.067"	100 cm
9-PLUG-014	14 mm	8 mm	6 French	.067"	100 cm
9-PLUG-016	16 mm	8 mm	6 French	.067"	100 cm

* For use with standard guiding catheters meeting minimum internal diameter requirements.

Intended Use:
The AMPLATZER Vascular Plug is indicated for arterial and venous embolizations in the peripheral vasculature.

Predicate Devices:
The AMPLATZER Vascular Plug is similar to many devices already in commercial distribution for arterial and venous embolization. These devices include an Embolization Coil Positioner Set (COOK, Incorporated), Flipper Detachable Coil (COOK, Incorporated), Fibered Platinum Coil (Boston Scientific Target), and Guglielmi Detachable Coil (Boston Scientific Target). The devices

are introduced percutaneously using a catheter or microcatheter introducer. The following is a comparison of technological characteristics. Also refer to Table 6-1 for summary of Technological Characteristics.

The Embolization Coil Positioner Set was reviewed as substantially equivalent under D.C. K940189 and is indicated for arterial and venous embolization. The device is constructed of stainless steel and synthetic fiber with a coil wire diameter of 0.018 to 0.038 inches. The coils are available in straight or curled shapes with an emboli size range of 2 to 20 mm. A push-button release mechanism is the method of deployment.

The Flipper Detachable Coil was reviewed as substantially equivalent under D.C. K993455 and is indicated for arterial and venous embolization for the peripheral vasculature. The device is constructed of stainless steel and synthetic fiber with a coil wire diameter of 0.035 inches. The coils are available in curled shapes with an emboli diameter range of 3 to 8 mm. Deployment is achieved when interlocking threads between the coils and the delivery wire are unscrewed.

The Fibered Platinum Coil was reviewed as substantially equivalent under D.C. K955293 and is indicated for arterial and venous embolization in the peripheral vasculature. The device is constructed of platinum and synthetic fiber with a coil diameter of 0.010 to 0.035 inches. The coils are available in the following shapes: straight, C-shaped, helical and complex helical. The emboli size range is 2 to 30 mm. Deployment is achieved by a wire guide which pushes the coil out of the catheter.

The Guglielmi Detachable Coil was reviewed as substantially equivalent under D.C. K951256, K960705 and K962503 and is indicated for embolization of intracranial aneurysms, arteriovenous malformations, arteriovenous fistulae and arterial venous embolizations in the peripheral vascular. The device is constructed of platinum with a coil wire diameter of 0.010 to 0.018 inches. The coils are available in a helical shape with an emboli size range of 2 to 20 mm. The coils are deployed by electrolytic detachment from the wire guide.

Table 6-1 Summary of Technological Characteristics Compared to Predicate Device

Device	Design	Coil wire diameter	Shape
COOK, Embolization Coil Positioner Set	Stainless steel and synthetic fiber	0.018 – 0.038"	Straight or curled
COOK, Flipper Detachable Embolization Coil	Stainless steel and synthetic fiber	0.035"	Curled
Boston Scientific Target, Fibered Platinum Coil	Platinum and synthetic fiber	0.010 - 0.035"	Straight, C-shaped, helical; and complex helical
Boston Scientific Target, Guglielmi Detachable Coil	Platinum	0.010 – 0.018"	Helical
AMPLATZER Vascular Plug	Nitinol wire	.0015" - .003"	Cylindrical, "plug"

Safety and Performance:

Animal Testing was conducted to evaluate the efficacy and recanalization rates of the AMPLATZER Vascular Plug as compared to standard coils. All procedures were performed successfully without misplacement. The following results were obtained:

- Occlusion time was significant shorter with the AMPLATZER Vascular Plugs as compared to Cook coils (5.0 ± 3.5 minutes vs. 10.2 ± 9.8 minutes, $P < 0.001$).
- Technically, positioning of the coils was far less precise than positioning of the AMPLATZER Vascular Plugs. Recanalization occurred with both the plugs and coils, but was more prominently seen in the coil group (33% and 80% at 1 week and 1 month vs. 15% and 78% for plugs) although it is well known from clinical practice that recanalization of coils embolized vessels in human subjects is exceedingly rare. The higher incidence of recanalizations in canines is due to the more active fibernolitic system of this species.
- Occluder stability was assessed immediately following deployment. No migrations occurred.
- At 2 months, all vessels occluded with coils (100%) had become recanalized compared to 16 out of 18 (88%) with the AMPLATZER Vascular Plug.
- Gross examination of occluded vessels showed all AMPLATZER Vascular Plugs to be well endothelialized and firmly attached to the vessel wall, whereas spring coils were easy to shell out.

Bench testing was done to evaluate the ability of the AMPLATZER Vascular Plug and Delivery System to perform in accordance with the requirements of the design plan.

AMPLAZER Vascular Plug Test Results:

- **Vascular Plug Elongation Study** – Linear measurements of the Vascular Plug prior to and under a compression restraint.
- **Pull Testing** - Laser Welded Marker Bands on Vascular Plug
- **Pull Testing** – Screw Attachment to Marker Band Laser Weld
- **Threaded Connection Pull Testing** – Pull testing to verify the strength property of the connection in between the delivery cable screw and the device end screw attachment.
- **Vascular Plug** – detachment (unthreading) from delivery cable.

AMPLATZER Delivery System Test Results:

- **Pull Test Weld Joint – Cable to Cable Screw** – Verify weld strength
- **Luer Testing** – Loader hubs were subjected to ISO 594 luer testing.
- **Loader** – Hub to PTFE tubing tensile strength – Pull tested until hub separation from the loader tubing.
- **Loader Hub Luer Fitting** – Hoop dispenser and loader will allow flushing with a syringe.
- **Passage and Deployment through 5F or 6F Guide Catheters** – Measure advancement force in the catheters.

The following Biocompatibility Testing was performed.

- Cytotoxicity
- Hemolysis
- Sensitization
- Ames Salmonela
- Intracutaneous Injection
- Systemic Toxicity

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use for arterial and venous embolization in the peripheral vasculature.

Statement of Equivalence:

The AMPLATZER Vascular Plug is substantially equivalent in intended use to currently marketed coils indicated for arterial and venous embolizations in the peripheral vascular. The proposed device is substantially equivalent to the Embolization Coil Positioner Set (COOK, Incorporated), Flipper Detachable Embolization Coil (COOK, Incorporated), the Fibered Platinum Coil (Boston Scientific Target), and the Guglielmi Detachable Coil (Boston Scientific Target).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2003

AGA Medical Corporation
c/o Mr. Patrice M. Stromberg
682 Mendelssohn Avenue
Golden Valley, MN 55427

Re: K031810
AMPLATZER® Vascular Plug
Regulation Number: 21 CFR 870.3300
Regulation Name: Arterial embolization device
Regulatory Class: Class III (three)
Product Code: 79 KRD
Dated: June 11, 2003
Received: June 12, 2003

Dear Mr. Stromberg:

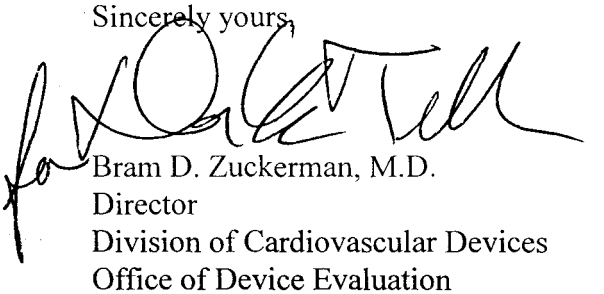
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031810

Device Name: AMPLATZER Vascular Plug

Indications For Use:

The AMPLATZER Vascular Plug is indicated for arterial and venous embolizations in the peripheral vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Only

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031810